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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,767	10/30/2001	Edward M. Atkinson	226272003310	3324

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,767

Applicant(s)

ATKINSON ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8- 34, 50, 51, 53- 92, 118, 119, and 159- 162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8- 34, 50, 51, 53- 92, 118, 119, and 159- 162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to Amendment B filed 11 October 2002. Claims 8- 34, 50, 51, 53- 92, 118, 119, and 159- 162 are under consideration.

Response to Amendment

Rejections and Objections Withdrawn

All objections are withdrawn because they are moot in light of the amendment.

The rejections under 35 USC 112, second paragraph, are withdrawn because they are moot in light of the amendment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections of record are withdrawn and new rejections set out below.

Rejections- New

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 8, 9, and 17- 20 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Riordan (WO 97/08298).

These claims are drawn to a method of purifying rAAV particles from cell lysate or supernatant by steps including anion and cation chromatography.

O'Riordan discloses a method of purification of rAAV as claimed. For purification of rAAV, O'Riordan uses filtration to clarify lysates and ion-exchange and other types of columns to purify and concentrate the particles (pages 17- 21). In a "particularly preferred embodiment" the sequential combination chromatography is disclosed cation then anion (page 21, lines 11- 15).

Claim Rejections - 35 USC § 103

Claims 10- 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan (WO 97/08298).

O'Riordan as discussed above teaches the use of multiple columns including cation and anion chromatography as well as hydroxyapatite columns.

It would have been obvious to one of ordinary skill in the art and a matter of routine laboratory optimization to change the order of columns in the protocol of O'Riordan to obtain AAV with a higher level purity.

Claims 13- 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan (WO 97/08298).

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O'Riordan as discussed above teaches the use of multiple columns including cation and anion chromatography as well as filtration.

While O'Riordan does not teach tangential flow filtration specifically for AAV, it is taught as a method concentrate adenovirus.

Tangential flow filtration is known in the art as way to concentrate a sample and has been used for viruses. It would have been obvious to one of ordinary skill in the art to process the fluid samples of virus to facilitate the handling of larger volumes of fluid when doing column chromatography.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan (WO 97/08298) and Graham (*J. Gen. Virol.* 1987, vol. 68 pages 937- 940).

O'Riordan as discussed above teaches the use of multiple columns including cation and anion chromatography.

Graham teaches that cells grown in suspension offer advantages over cells grown in monolayers in terms of efficiency, economy and potential automation of large scale production (page 939, last paragraph).

Thus, it would have been obvious to one of ordinary skill in the art to increase the amount of AAV to be purified by the method of O'Riordan by using the cell culture method of Graham.

Claims 50, 51, 53- 92 rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan (6/3/1997, WO 97/08298, from IDS), as applied to claims 8, 9, and 17-

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20 above and Graham as applied to claim 21 above, and further in view of Shenk (US Pat 5,346,146).

These claims are drawn to a method of producing rAAV particles and purifying them by chromatography.

O'Riordan as discussed above teaches purification of AAV using anion and then cation chromatography as well as filtration, nuclease treatment, concentration of sample. O'Riordan additionally teaches the use of microfluidization (page 36, line 18) and Benzonase (page 17, line 33).

O'Riordan does not teach the method of producing AAV recombinants.

Shenk discloses a method of producing a rAAV by cotransfecting producer cells having a heterologous DNA flanked by at least one inverted terminal repeat (ITR), helper AAV DNA coding one or more AAV packaging proteins needed for replication and encapsidation, and helper virus, in this case adenovirus (Column 12, lines 49- column 13, line 12). Shenk also teaches that AAV helper genes can be linked to a variety of promoters/and regulatory sequences including inducible promoters (columns 11-12), packaging genes can be stably integrated into the producer cell (column 12, lines 6- 38) and introduction of rAAV vector can be done prior to infection, simultaneously to infection, or after infection (column 12, lines 60- 64).

Graham teaches that cells grown in suspension offer advantages over cells grown in monolayers in terms of efficiency, economy and potential automation of large scale production (page 939, last paragraph).

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It would have been obvious to one of ordinary skill in the art to use a known method to construct rAAV such as the method of Shenk to make AAV to purify by the method of O'Riordan because O'Riordan only teaches purification and scale up the cell culture with the advantages as taught by Graham.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22- 34, 118, 119, and 159- 162 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 126 and 159- 162 of Allowed U.S. Patent Application No. 09/526,333. Although the conflicting claims are not identical, they are not patentably distinct from each other because AAV is purified from the supernatant without a lysis step using anion and cation chromatography.

In *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 16 USPQ2d 1436, the Court of Appeals Federal Circuit ruled that the prohibition of Double Patenting after Restriction is not absolute, and double patenting protection of section 121 does not apply where the claims have been changed in material respect from the restriction requirement. Reviewing the prosecution history in parent application 09/526,333, the restriction between groups III and VII was made on the basis that group III involved a method to purify rAAV using cationic and anionic chromatography, while group VII involved releasing rAAV from cells. However, during prosecution of elected group VII in application 09/526,333, at least one claim was changed in material respect, in that the group VII feature of purifying AAV from the supernatant without a lysis step using anion and cation chromatography, resulting in allowed claim 126. Since patent claim 126 was not consonant with the original restriction requirement, and since the instant claims are drawn to obvious embodiments encompassed by allowed claims 126 and 159- 162, a double patenting rejection is proper.

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Conclusion

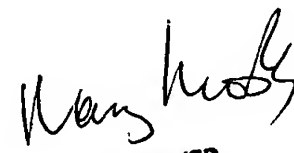
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
January 21, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600